ATTACHMENT 77

From: Glenn P
Sent: Friday, July 22, 2022 9:12 AM PDT
To: Lee, Anthony; Rick Lyon; Chris G
CC: Bittleman, Katelyn
Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee.
Thank you for clarifying this issue for us. We very much appreciate your assistance. Have an enjoyable weekend.
Very best,
Glenn
Glenn Papit
Vice President
Rebotix Repair
407-810-4176
https://www.rebotixrepair.com
From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Friday, July 22, 2022 10:19 AM
To: Rick Lyon <rick@dovel.com>; Chris G <chris@rebotixrepair.com>; Glenn P <glennpapit@rebotixrepair.com>
Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rebotix team,

In my prior communications below, specifically in my email dated Wednesday, April 06, 2022 5:58 AM in reference to CPT2000126, I used the term "decision" in a manner that may have incorrectly implied that FDA had made an official regulatory determination related to Rebotix, which Rebotix has now suggested it wants to "appeal." To clarify, FDA conducted a preliminary **informal assessment** of the limited materials previously provided by Rebotix, and FDA has not conducted an official regulatory evaluation.

Informal communications with FDA staff do not represent the formal position of FDA and do not bind or otherwise obligate or commit the agency to the views expressed. This is why there is nothing for Rebotix to appeal at this time. For additional information on appeals that would be available once an official regulatory determination has issued, please see FDA guidance, "Center for Devices and Radiological Health (CDRH) Appeals Process" (https://www.fda.gov/media/128444/download).

If you wish to receive a regulatory evaluation of Rebotix's materials, we encourage you to submit an application such as a 510(k).

Thank you for your time and willingness to participate in our recent interactions.

Best regards,
Anthony Lee

Anthony Lee, PhD, MBA

Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

U.S. FOOD & DRUG ADMINISTRATION

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Lee, Anthony
Sent: Friday, April 8, 2022 2:28 PM
To: Rick Lyon <rick@dovel.com>; Chris G <chris@rebotixrepair.com>
Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rick and Chris,
Thank you for your time earlier today. As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted.

The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. This includes, but is not limited to, items such as electrical safety, reprocessing, software, and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition.

Please let us know if you have any further questions and what your intentions are for next steps.

Thank you again,
Anthony

Anthony Lee, PhD, MBA
Team Lead

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From: Rick Lyon <rick@dovel.com>
Sent: Wednesday, April 6, 2022 1:13 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Thank you, Anthony. 1 PM ET works for us. What is the best number to reach you? Or if you prefer, I can send call-in information.

Thanks,
Rick

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Wednesday, April 06, 2022 5:58 AM
To: Rick Lyon <rick@dovel.com>
Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rick,
A decision has been made regarding CPT2000126 and Rebotix Repair. We would like to request a short teleconference. Are you and someone from Rebotix available to discuss this Friday at 1PM ET?

Thanks,
Anthony

Anthony Lee, PhD, MBA
Team Lead

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From: Lee, Anthony
Sent: Monday, December 13, 2021 10:56 AM
To: Rick Lyon <rick@dovel.com>
Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Good morning Rick,
We have discussed your request internally, and we are ok with extending the response by an additional 30 days. We look forward to hearing back from you in January.

Regards,
Anthony

Anthony Lee, PhD, MBA
Team Lead

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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Rick Lyon <rick@dovel.com>
Sent: Friday, December 10, 2021 11:51 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Chris G <chris@rebotixrepair.com>
Subject: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee,

Thank you for taking the time to speak with me. Following up on our conversation, would it be possible to extend the deadline for our submission of the information you requested by 30 days? This would make the information due January 15, 2022, instead of next Thursday (December 16, 2021).

Best regards,
Rick Lyon
310-656-7066
Counsel for Rebotix Repair LLC